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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,308	08/20/2003	Jill Giles-Komar	CEN309 USA NP	6015

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,308	GILES-KOMAR ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/16/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *5, 8, 12, and 14 -19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-7, 9-11, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of species, in the reply filed on 9/16/05 is acknowledged. Applicant has elected the method including administering an expansion agent, and not administering a CD40 agonist. Applicant has also elected type I interferon as the dendritic cell maturation agent, and a BALB/c mouse. Applicant states that Claims 1-3, 6-7, 9-11 and 13 read on the species elected. Claim 4 is also being included, since it reads on the elected species due to the open claim language (i.e. comprising). However, Claim 4 is only being examined as it reads on including a dendritic cell expansion agent. Claims 5, 8, 12, and 14-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 1-4, 6-7, 9-11, and 13 read on the elected invention and are being acted upon.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 4, 6-7, 9-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pulendran et al. in view of Le Bon et al.

Pulendran et al. teaches a method for generating antigen specific antibodies in Balb/c mice comprising the steps of administering the dendritic cell expansion agent Flt3 ligand, immunizing said mice with an antigen, and measuring the level of antigen-specific antibodies present in the serum (see Fig. 5). Since the serum was isolated from the mice, and contains antigen-specific antibodies, said antibodies have been isolated, as recited in step d) of the instant claims.

Pulendran does not teach administering a dendritic cell maturation agent such as Type 1 interferon.

Le Bon et al. teaches that Type 1 interferons can enhance the in vivo antibody response to an antigen. Le Bon specifically teaches administering a combination of IFNα and IFNβ (i.e. a combination of dendritic cell maturation agents, as recited in Claim 7 of the instant application).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the maturation agents IFNα and IFNβ, as taught by Le Bon, in the method of generating antibodies as taught by Pulendran. The ordinary artisan at the time the invention was made would have been motivated to do so to achieve an improved response, since Le Bon demonstrates that IFNα and IFNβ are potent adjuvants for augmenting the primary antibody response, generating memory responses, and inducing class switching (see pg. 467). Moreover, one of ordinary skill in the art would have had a reasonable expectation of success combining the adjuvant effect of IFNα and IFNβ, as taught by Le Bon, with the method of generating antibodies, as taught by Pulendran.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pulendran et al. and Le Bon et al., as applied to claims 1-2, 6-7, and 9-11 above, and further in view of Daro et. al.

The combined teachings of Pulendran and Le Bon are discussed above.

Pulendran and Le Bon do not teach administering Flt3L in combination with another dendritic cell expansion agent.

Daro teaches administration of Flt3L in combination with GM-CSF. Since Daro teaches that GM-CSF can induce expansion of dendritic cell numbers (see pg. 120), it can be considered to be a dendritic cell expansion agent.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use GM-CSF and FLt3L as taught by Daro, for the method of generating antibodies as taught by Pulendran and LeBon. The ordinary artisan at the time the invention was made would have been motivated to do so, and would have had a reasonable expectation of success, since Daro teaches that co-

administration of Flt3L and GM-CSF yields greater numbers of dendritic cells than either cytokine alone (see pg. 125).

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
September 30, 2005

10/25/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER